SECTION 3 -- 510K SUMMARY

Submitter:	Arrow International, Inc. 2400 Bernville Road Reading, PA 19605
Contact person:	Debra A. Peacock Regulatory Associate Phone: (610) 378-0131, ext. 3368 Fax: (610) 374-5360 E-mail: debbie.peacock@arrowintl.com
Date summary prepared:	April 3, 2002
Device trade name:	Radial Artery Catheterization Set with Integral Needle Protection.
Device common name:	Radial artery catheterization set.
Device classification name:	Percutaneous catheter
Legally marketed devices to which the device is substantially equivalent:	Arrow Radial Artery Catheterization Set (K810675), and the Arrow PICC Two-lumen Peripherally-inserted Central Catheter Kit with Blue Flex Tip® Catheter and Integral Needle Protection (K003006).
Description of device:	The proposed device is a sharps-protected version of the Arrow Radial Artery Catheterization Set. It contains a radial artery catheter-over-needle assembly with an integral, passive needle protection feature.
Intended use of the device:	The Arrow arterial catheterization device permits access to the peripheral arterial circulation. The safety feature is intended to help minimize the risk of sharps injuries when using the device.
Technological characteristics:	The proposed needle-protected RA device has the same technological characteristics as the predicate devices including design, packaging, sterilization and labeling.
Performance Tests	The following tests were performed to demonstrate substantial equivalence: • Device reliability • Clinical simulation • Deactivation force of safety feature • Safeguard interference fit • Tensile • Corrosion

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 2 2002

Ms. Debra A. Peacock
Regulatory Associate
Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605

Re: K021120
Radial Artery Catheterization Set with Integral Needle Protection
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: April 3, 2002
Received: April 8, 2002

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7 – INDICATIONS FOR USE STATEMENT

510(k) Number: K021120

Device Name: Radial Artery Catheterization Set with integral needle protection

Indications for Use: The Arrow arterial catheterization device permits access to the peripheral arterial circulation. The safety feature is intended to help minimize the risk of sharps injuries when using the device.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021120